UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA *et al.* *ex rel.* JULIE LONG, Plaintiffs, v. JANSSEN BIOTECH, INC., Defendant.	Civil Action No. 16-CV-12182-FDS

RELATOR'S RESPONSE OBJECTING IN PART TO DEFENDANT'S SECOND REQUEST FOR A STATUS CONFERENCE AND TO IMPOSE A DEADLINE FOR RELATOR'S FORTHCOMING MOTION TO COMPEL

Plaintiff-relator Julie Long submits this response to defendant Janssen Biotech's second Request for a Status Conference and request to impose a deadline for Relator's forthcoming motion requesting that Janssen, as a matter of fairness, be required to fully disclose the legal advice it received concerning whether the free services provided to select physicians violated the Anti-Kickback Statute ("AKS") and False Claims Act ("FCA").

Relator Does Not Oppose Janssen's Request That A Status Conference Be Scheduled

Relator agrees that a status conference is necessary in order to obtain the Court's guidance on the phase one discovery schedule, including issues that impact the schedule, as well as other issues concerning the phase one summary judgment process, and therefore does not object to Janssen's request that a status conference be scheduled. However, as she stated in responding to Janssen's first request for a status conference, Relator objects to the schedule Janssen proposes because it entirely disregards the phased discovery approach governing this action and, if entered, would be unfair and prejudicial to Relator. *See* Pl.'s Resp. to Oct. 2, 2023

Req. for Status Conf. (ECF 411). In further regard to Janssen's proposed end date for phase one discovery of April 26, 2024, that date is now unachievable because of the emergence of new issues, which as explained below, impact depositions and necessitate additional discovery. Moreover, like its first status conference request, Janssen's second request is unconstructive because it does not identify the specific issues that need to be reviewed with the Court and addressed before a fair and appropriate schedule can be set.

The issues that Relator identified in her response to Janssen's first request for a status conference still must be addressed. *See* Pl.'s Resp. to Oct. 2, 2023 Req. for Status Conf. (ECF 411) at 2-6. Those issues, which are described in more detail in Relator's response to Janssen's first request for a status conference, include:

(1) The number of depositions that will be permitted during phase one fact discovery;

(2) The end date for phase one fact discovery;

(3) How the Court would like for the parties to proceed in presenting any expert testimony that they may rely on in support of, or in opposition to, Janssen's phase one summary judgment motion;

(4) The process for deposing any experts whose testimony is presented in support of, or in opposition to, Janssen's phase one summary judgment motion; and

(5) When the parties will be required to disclose all expert testimony that they may use at trial.

Two additional issues have emerged that must also be reviewed during the status conference because they impact scheduling:

(1) Relator's forthcoming motion to compel full disclosure of the legal advice Janssen received concerning whether the free services at issue violated the AKS or FCA; and

(2) Following the disparate rulings in *United States v. Regeneron Pharm., Inc.*, 1:20-cv-11217-FDS (D. Mass.) and *United States v. Teva Pharm. USA, Inc.*, 1:20-cv-11548-NMG (D. Mass.), the current uncertainty as to the applicable standard for proving that an FCA violation "resulted from" an AKS violation.

Phase One Discovery Can No Longer Be Completed By Early Spring

In early October, when Relator submitted her response to Janssen's first request for a status conference, she had hoped that phase one discovery could be completed by early Spring. Since then, however, it has become clear that additional discovery will be required that makes an early Spring end date unachievable.

Janssen did not complete its production of the substantial volume of documents and privilege log (to which it added over 3,000 new entries) that it was ordered to produce in March 2023 until mid-October, causing Relator's ability to recommence taking depositions to be delayed to late November. Relator promptly deposed four higher-level former Janssen employees before the December holidays. Based on the witnesses' testimony and new discovery, it has become evident that Janssen is trying to use the attorney-client privilege as both a sword and shield by partially disclosing select legal advice and asserting an affirmative defense that it had a good faith belief that providing the free services at issue did not violate the AKS while at the same time blocking Relator from obtaining information concerning other privileged communications that would reveal the actual legal reviews Janssen performed and legal advice it received concerning whether providing the services at issue at violated the AKS. Janssen's abuse of the attorney-client privilege in an effort gain an unfair advantage and bury the truth is the subject of a forthcoming motion that will be filed on or before January 24.

Because Janssen's knowledge regarding the wrongfulness of its conduct—an element of Relator's AKS claims as well as an issue Janssen itself raised through its good faith belief defense—is one of the principal issues and disputes in the case, Janssen's misuse of the privilege must be addressed before proceeding with additional witness depositions. It would be highly inefficient, and indeed counterproductive, to continue taking depositions before the

waiver issue is decided given that one of the main areas of focus and questioning will be Janssen's knowledge concerning the legality/illegality of providing the free services at issue. This is particularly true given Janssen's counsel's instructions to witnesses to not answer questions relevant to Janssen's knowledge of the legality/illegality of the free services during the depositions, claiming that the information is privileged. Addressing the waiver dispute now, could in fact shorten the length of the discovery period and make it more efficient, as it allows the most knowledgeable witnesses to be deposed, including Janssen's attorneys, who, according to Janssen's partial disclosures, approved of the provision of the free services to physicians, and also avoids creating a situation where other witnesses would need to be deposed multiple times.

Janssen feigns that it is harmed by the time that this motion will add to the length of the phase one discovery period. This assertion is not only baseless, it is farcical. It is Janssen's abuse of the attorney-client privilege in an attempt to gain an unfair advantage that necessitates this motion. And more generally, as memorialized in the Court's numerous discovery orders[1], it is Janssen's flouting of its discovery obligations and evasiveness that have slowed and stretched out this initial discovery period. Thus, it is Relator and the United States—for which Relator is litigating these claims—that have been prejudiced by Janssen's tactics. As much as Relator wishes to conclude phase one discovery, move past the phase one summary judgment proceeding, and get ready for trial, Relator will not forego critical discovery in order to conclude phase one discovery a few months sooner.

[1] *See, e.g.,* Dec. 20, 2021 Order (ECF 237); Feb. 17, 2022 Order (ECF 282) at 15 (denying Janssen's motion to reconsider the Dec. 20, 2021 Order); Sep. 9, 2022 Order (ECF 320) (affirming in part the Feb. 17, 2022 Order); Mar. 9, 2023 Order (ECF 375) at 6-9 (ordering compliance with the prior orders).

Furthermore, the current uncertainty regarding the applicable standard for proving that the alleged false claims for Medicare reimbursement "resulted from" the alleged AKS violations places into question the discovery that will be required to meet such standard. Should the First Circuit adopt the standard this Court set forth in *United States v. Regeneron Pharm., Inc.*, Civ. No. 20-11217-FDS, 2023 WL 6296393, at *7-11 (D. Mass. Sep. 27, 2023) (Saylor, C.J.), then Relator will likely need additional discovery concerning the impact that the free services had on physicians' decisions to prescribe Janssen's drugs Remicade and Simponi ARIA to Medicare beneficiaries. Accordingly, this issue should also be considered as part of the discussion of a fair and appropriate schedule.

The Court Should Deny Janssen's Unnecessary Request To Impose A Due Date For Relator's Forthcoming Motion To Compel Full Disclosure Of Legal Advice Regarding Whether The Free Services At Issue Violated The Anti-Kickback Statute

Relator's forthcoming motion is not unduly delayed and will be filed on or before January 24. Accordingly, Janssen's motion was unnecessary and should be denied.[2]

Dated: January 19, 2024

Respectfully submitted,

/s/ Theodore J. Leopold

Theodore J. Leopold (admitted pro hac vice)
Leslie M. Kroeger (admitted pro hac vice)
Diana L. Martin (admitted pro hac vice)
Poorad Razavi (admitted pro hac vice)
COHEN MILSTEIN SELLERS & TOLL PLLC
11780 U.S. Highway One, Suite N500
Palm Beach Gardens, FL 33408
(561) 515-1400
tleopold@cohenmilstein.com
lkroeger@cohenmilstein.com
dmartin@cohenmilstein.com
prazavi@cohenmilstein.com

[2] It should be noted that if Janssen had advised Relator that it was going to ask the Court to impose a due date for her motion, an obligation it disregarded, Relator would have provided it a specific date by which the motion will be filed.

Casey M. Preston (admitted pro hac vice)
Gary L. Azorsky (admitted pro hac vice)
Jeanne A. Markey (admitted pro hac vice)
Adnan Toric (admitted pro hac vice)
COHEN MILSTEIN SELLERS & TOLL PLLC
100 N. 18th Street, Suite 1820
Philadelphia, PA 19103
(267) 479-5700
cpreston@cohenmilstein.com
gazorsky@cohenmilstein.com
jmarkey@cohenmilstein.com
atoric@cohenmilstein.com

Jonathan Shapiro (BBO No. 454220)
SHAPIRO & TEITELBAUM LLP
90 Canal Street, Suite 120
Boston, MA 02116
(617) 742-5800
jshapiro@jsmtlegal.com

Counsel for Plaintiff-Relator Julie Long

Certificate of Service

I hereby certify on this 19th day of January, 2024, that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Theodore J. Leopold
Theodore J. Leopold (admitted pro hac vice)